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AUDIT REPORT FOR DENMARK
JANUARY 30 THROUGH FEBRUARY 28, 2002

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Denmark's meat inspection system from January 30 through February 28, 2002. Eleven of the 90 establishments certified to export meat to the United States were audited. One of these was a slaughter establishment, two were slaughter and processing establishments; five were conducting processing operations, and the remaining three establishments were cold storage facilities.

The last audit of the Danish meat inspection system was conducted in March-April 2001. Nine establishments were audited on-site. The auditor found serious deficiencies in two establishments (Ests. 71 and 190) that were then designated as marginal/re-review during the next audit. The concerns at that time included the following:

- Pre-shipment document reviews had not been developed and implemented in one of the nine establishments visited on-site, or in nine of the 16 establishments for which document reviews were performed.
- Maintenance and cleaning of over-product equipment had been neglected in four of the nine establishments visited.
- Additional sanitizers were required in essential locations in two establishments.
- Condensation controls were inadequate in two establishments.
- Light was inadequate in the retained carcass inspection areas in two establishments.
- Documentation of Sanitation Standard Operating Procedures was inadequate in two establishments.

Beef products were ineligible for export to the U.S. at the time of this audit, due to the presence of Bovine Spongiform Encephalopathy in Denmark. The only restriction on pork products was that the products must be indigenous and processed in dedicated establishments that receive no animals from countries where Foot-and-Mouth Disease and Swine Vesicular Disease exist (these conditions were fulfilled in Denmark).

During calendar year 2001, Danish establishments exported 117,205,257 lbs. of pork and pork products to the U.S. Of these products, 35,535,905 lbs. were reinspected at U.S. ports

of entry; a total of 434,349 lbs. (slightly more than 1.22% of the reinspected products) were rejected. The reasons for the rejections, in reverse order of volume, were processing defects (0.43% of the amount reinspected), contamination (0.34%), pathology (0.17%), transportation damage (0.10%), and missing shipping marks (negligible).

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Danish national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in several of the Danish Veterinary and Food Administration's regional headquarters offices. The third was conducted by on-site visits to establishments. (The two establishments that had been evaluated as acceptable/re-review during the previous audit were visited again; the remainder of the establishments selected for on-site audits and those selected for document audits were chosen randomly.) The fourth part involved visits to one government laboratory performing analytical testing of field samples for the national residue testing program, and one private laboratory culturing field samples for the presence of microbiological contamination with *Salmonella* species and *Escherichia coli (E. coli)*.

Denmark's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials (one of the establishments audited at this time fell into this category).

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in nine of the establishments audited on site; two others (Ests. 34 and 190) were found to be unacceptable. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* species and generic *E. coli,* are discussed later in this report.

As stated above, among the concerns that had been identified during the last audit of the Danish meat inspection system, conducted in March-April 2001, were the following:

- *Pre-shipment document reviews had not been developed and implemented in one of the nine establishments visited on-site, or in nine of the 16 establishments for which document reviews were performed.* During this new audit, pre-shipment document reviews had been developed and implemented in all establishments, although not until very recently in three (see the Monthly Reviews section of this report for details).

- *Maintenance and cleaning of over-product equipment had been neglected in four of the nine establishments visited.* During this new audit, similar problems were found in four of the 11 establishments visited; this was a repeat finding.

- *Additional sanitizers were required in essential locations in two establishments.* This had been adequately addressed and corrected.

- *Condensation controls were inadequate in two establishments.* During this new audit, no serious condensation problems were found.

- *Light was inadequate in the retained carcass inspection areas in two establishments.* During this new audit, light was again found to be inadequate in two establishments; this was a repeat finding.

- *Documentation of Sanitation Standard Operating Procedures was inadequate in two establishments.* During this new audit, similar problems were again identified in one establishment; this was a partial repeat finding.

In addition, the following major concerns arose as a result of this current audit of Denmark's meat inspection system:

- Visible fecal contamination was found on product that had passed all establishment and DVFA inspection controls in two of the 11 establishments audited on-site. Also, in these two establishments, the written controls for enforcement of the zero-tolerance policy for visible fecal contamination were not followed as required.

- For the 30 establishments whose documents were audited, during the year prior to this audit, monthly supervisory internal reviews had not been conducted as required for one month in each of four establishments, for three months in each of three establishments, and for five months in one establishment.

- Inadequate cleaning of product-contact equipment before use was found in three of the seven establishments in which exposed product was handled.

Entrance Meeting

On January 30, an entrance meeting was held in the Mørkhøj offices of the *Danish Veterinary and Food Administration (DVFA)*, and was attended by Dr. Birgitte Povlsen, Senior Veterinary Officer and Head of the Division for Import/Export; Dr. Jens Munk Ebbesen, Deputy Head of the Division for Import/Export; Dr. Mette Nyborg, Veterinary Officer and Deputy Head of the Division for Food Safety; Dr. Henning Pedersen, Veterinary Officer, Division for Import/Export; Ms. Susanne J Jensen, Food Scientist, Division for Food Safety; and Ms. Lisbeth Ott-Ebbesen, Food Scientist, Division for Control Coordination. USDA's Food Safety and Inspection Service was represented by Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS; and Mr. Richard Brown, Equivalence Officer, International Policy Staff. Topics of discussion included the following:

1. Details of the itinerary were discussed and finalized.

2. The Auditor explained how and when the draft report generated as a result of this audit would be submitted, how the Danish officials' comments would be incorporated into the report, and how and when the report would be finalized.

3. The Auditor provided the DVFA officials with statistics for Danish products presented, reinspected, and rejected at U.S. ports of entry during calendar year 2001.

4. The auditor presented a summary of the findings of the previous FSIS audit of Denmark's meat inspection system, conducted in March-April 2001.

5. There were a few changes in the DVFA organizational structure and upper-level staffing. A new organizational chart was presented.

Headquarters Audit

There had been a few changes in the organizational structure since the last U.S. audit of Denmark's inspection system in September 2000. A new organizational chart was provided.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The Auditor conducted audits of inspection system documents pertaining to the establishments listed for records review. These records audits were conducted at several of the regional offices. The records review focused primarily on food safety hazards and included the following:

- Monthly internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.

- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing, and *Salmonella* testing.
- Export product inspection and control.

The concerns from the examination of these documents will be described later in this report.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Denmark as eligible to export meat products to the United States were full-time employees of the Danish Food and Veterinary Administration (DVFA), receiving no remuneration from either industry or establishment personnel.

The Danish Ministry for Food, Agriculture, and Fisheries was comparable to the Department of Agriculture in the United States. The Ministry was divided into 4 departments, including the Food and Environment Department (FED). Within FED was the Veterinary and Food-stuffs section, which contained the Danish Veterinary and Food Administration (DVFA). Within DVFA were the Danish Veterinary Service, the Food Control Department, Administration, and the Danish Veterinary Laboratory/Institute. Also within DVFA, and directly under the control of the Director General for DVFA, were the eleven Regional Veterinary and Food Control Authorities (RVFCAs). In general, the eleven Regional Authorities had the same four Departments. Within the Food Control Department of each RVFCA were the Chief Veterinarians, who served as field supervisors over the resident veterinarians and inspectors within one or more certified establishments and other facilities.

DVFA in Mørkhøj served as the implementation, control, and coordination center for the Danish meat inspection system and was responsible for monitoring the country's food supply. The Food Control Departments (FCD) of DVFA and RVFCA managed most wholesale- and retail-outlet inspections and product sampling. In addition, the Veterinary Services (VS) handled port-of-entry (POE) inspections and rendering facilities. All animal health problems noted by FCD must be reported to the VS.

The distribution, implementation, and maintenance of new FSIS regulations or EC directives is critical in maintaining a viable government oversight system. New regulations were received by DVFA in Mørkhøj. If necessary, draft instructions or implementation procedures were developed here and distributed to all regional offices for comment. The final document was then completed and distributed for incorporation into the inspection system. This process was accomplished through the extensive use of e-mails, faxes, the Internet, phone calls, a monthly DVFA newsletter, and routinely-scheduled meetings between and among headquarters staff, regional staff, and groups of regional and national subject-matter experts. The flow and exchange of information in Denmark was commendable and enabled field employees to keep well-informed.

The Chief Veterinarians from each region were responsible for ensuring that new and previously-applied regulations and instructions are properly implemented and maintained by the resident veterinarians and inspectors in each certified establishment. Using a written set of basic guidelines developed by subject-matter experts within DVFA, the Chief Veterinarians incorporated regulatory changes into daily and periodic inspection tasks by altering previously-developed lists of tasks (including frequencies) to be performed by the resident veterinarians and inspectors. The performance of these tasks, and their frequency, were verified through review of the completed inspection reports. No reports were generated from these reviews. In addition, the frequency of tasks was not tabulated to ensure compliance, and the effectiveness of performing each task did not normally involve direct, over-the-shoulder supervision. Chief Veterinarians were, however, provided with the authority and flexibility necessary to address inspection problems on a case-by-case basis and were given considerable leeway regarding how to best supervise employees and implement and docu-ment inspection requirements and activities.

Chief Veterinarians were accountable to the Regional Food Control Department Director (FCDD), but they normally supervised each other by visiting each other's establishment(s) and facilities. These visits also served as the monthly supervisory visit required by FSIS. During these visits, the visiting Chief Veterinarian normally concentrated on reviewing the paperwork generated by the Chief Veterinarian visited and by his/her Resident Veterinarians and inspectors. Two reports were usually generated for each supervisory visit: an establishment inspection report and a supervisory report for the Chief Veterinarian visited, who was responsible for ensuring that the establishment corrected any noncompliance. A copy of these documents was filed at the regional office. In most instances, copies were not given directly to the FCDD or the Regional Director. The DVFA in Mørkhøj was advised of major establishment or supervisory findings, such as those involving fines, operational suspensions, or failure to use HACCP plans as required. Audits conducted by officials of the European Commission, FSIS, or others were used by the FCDD to supervise the Chief Veterinarians at their work sites and by the national office to supervise all non-headquarters personnel.

Chief Veterinarians, in general, were also responsible for certifying establishments for export to the United States. There were three categories of certification. First, small establishments can be and are approved for domestic production only. Second, all large, high-volume establishments and small establishments that export to other EU member countries must meet EC qualifications. Third, establishments exporting to non-EU countries, such as the United States, must be approved according to the applicable third-country requirements. Reports were prepared for each visit, thereby generating a certification history that can be reviewed by the regional or national office. Once the establishment is approved, a letter from the Chief Veterinarian is sufficient for the national office to place it on the U.S. export list. In contrast, the de-certification of establishments from U.S. export eligibility is usually confirmed and verified by the FCDD by direct discussions with the Chief Veterinarian and, if necessary, by an on-site visit. Often, the FCDD wrote the delistment letter and reported the delistment verbally to Mørkhøj as soon as possible. Although this system was very efficient in getting establishments certified and listed for export and in preventing unnecessary delistments,

national and regional authorities did not routinely substantiate the competence of the Chief Veterinarians by performing random, on-site reviews of their certification activities.

Overall, the implementation of Denmark's meat inspection system was remarkably similar to the FSIS system. However, there were differences regarding how the system's effectiveness was ensured and maintained. First, national and regional directors appeared to be somewhat reactive, rather than proactive, in maintaining an effective inspection system by relying on outside auditors to determine which establishments to review and, thereby, to discover establishment deficiencies and system failures. Second, supervision of field employees seemed to concentrate more on the paperwork produced than on the effectiveness or accuracy of the tasks assigned. In most cases, both are important. On a more positive note, the Danish officials had the resources and the evident desire to continually scrutinize and improve the effectiveness of the current system of government oversight.

Establishment Audits

Ninety-nine establishments were certified to export meat products to the United States at the time this audit was conducted. Eleven establishments were visited for on-site audits. In nine of the establishments visited, except as otherwise noted below, both DVFA inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories; intra-laboratory quality assurance procedures, including sample handling; and methodology.

The Fødevareregion Aarhus Laboratory in Aarhus was audited on February 20, 2002. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

The check sample program was designed to fulfill European Commission requirements. International check samples for organochlorines were provided by FAPAS in England and Quasimeme in Scotland and were performed usually four times per year for each method. None had yet been performed in 2002, but the first samples had been received and the results of analysis were scheduled to be submitted in April. The schedule also called for further samples in for heavy metals in May, July, October, and December 2002.

Arsenic had not been part of the sampling plan at the time of the March-April 2001 FSIS audit (new equipment was acquired five months previously and optimization was still ongoing), but testing for arsenic was now included in the routine program, along with lead, mercury, cadmium, and selenium.

All samples of animal origin listed in the 2001 national residue testing plan had been analyzed on schedule. There were no violative levels detected in 2001.

In the event that violative levels of residues are detected during routine sampling, the central DVFA authority in Copenhagen, the regional DVFA office, and the Veterinarian-In-Charge of the establishment of origin are notified immediately via telephone or e-mail, and sister samples are immediately submitted to the National Reference laboratory in Mørkhøj for confirmation. It is then the responsibility of the DVFA regional authorities to conduct traceback investigations. Concurrently, if there were indication that the violation could have more than local ramifications, the central authority would issue a "Rapid Alert Notification" to the European Commission.

The quality control system now included electronic documentation of the preparation of standard solutions (the information was entered from the individual work sheets prepared and signed by the analysts) and of comparison of new standard solutions with old ones before the new ones were used.

Denmark's microbiological testing for *Salmonella* was being performed in both private and government laboratories. One private laboratory, situated in the Danish Crown slaughter establishment in Herning, was audited on February 7. The auditor determined that the controls met the criteria established for the use of private laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

1. The laboratories have been accredited/approved by the government, accredited by third party accrediting organization with oversight by the government, or a government contract laboratory.
2. The laboratories have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
3. Results of analyses are being reported to the government or simultaneously to the government and establishment.

One concern arose as a result of this audit (see also Attachment E-2):

- According to Herning laboratory staff and the DVFA officials present at the audit, the four private laboratories in Herning, Horsens, Saeby, and Ringsted were using the EIA-Foss method and the NMKL (Nordic Methodic Committee for Foodstuffs) method for analysis of samples for *Salmonella*; this latter method is pretty much universally employed throughout Scandinavia. The other private laboratory, the TICAN laboratory in Thisted used a VIDAS method in addition to the NMKL method. In Herninng, The EIA-FOSS (Enzyme-Linked ImmunoSorbent Assay; Foss Electric, Hillerød, Denmark) method was used for samples received Mondays through Thursdays and the NMKL

method on Fridays for analysis for *Salmonella*. Any positives with the EIAFOSS method were confirmed with the NMKL method. Denmark had informed FSIS that the AOAC method for *Salmonella* was being used. The Equivalence Branch requires that they must be informed before any change in the methods used to fulfill the Pathogen Reduction requirements is made, so that an equivalence determination may be made. The Auditor informed the Danish officials that, until the new methods (NMKL, EIA-FOSS, and VIDAS) are submitted to FSIS and until such an equivalence determination is made, the AOAC method is to be used.

Establishment Operations by Establishment Number

The following operations were being conducted in the eleven establishments audited on-site:

Cattle slaughter – Est. 34
Cold storage – Ests. 165, 179, 191,
Swine slaughter, pork cutting – Est. 311
Blood (plasma) drying for pork protein – Est. 286
Pork cutting, boning, curing, drying, and smoking – Est. 469
Swine slaughter, pork cutting, boning, and ham production – Est. 71
Beef cutting, boning, and packing; pork packing; and cold storage – Est. 190
Freezing of fresh meat (pork and beef) in cartons and cold storage – Est. 172
Pork and beef cutting and boning; pork curing, drying. and smoking; cooked sausages – Est. 205

SANITATION CONTROLS

Based on the on-site audits of establishments, Denmark's inspection system had controls in place for chlorination procedures; back-siphonage prevention; sanitizers; separation of establishments, pest control programs and monitoring; temperature; operations and inspectors' work space; ventilation; dry storage areas; ante-mortem facilities; welfare facilities; outside premises; personal dress and habits; product reconditioning and transportation; and waste disposal.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs in the establishments visited were found to meet the basic FSIS regulatory requirements, with the exception of the following deficiency in the establishments visited on-site:

- In Est. 190, documentation of corrective actions was, at times, inadequate; preventive measures were not included in the corrective action documentation. Documentation by the Veterinarian-In-Charge indicated that the establishment's pre-operational sanitation inspections were inadequate approximately every second time he conducted his (bi-weekly) independent pre-operational sanitation checks.

Product Contamination

- The written plan in Est. 34 called for the designated carcass trimmer, whose position on the slaughter line was immediately after the carcass inspector, to document the incidence of fecal contamination. This was not being done. The establishment was relying on the DVFA final carcass inspector to document electronically the fecal contamination he observed, and the officials explained that, when the more than three out of ten consecutive carcasses were noted with fecal contamination, an alarm on the foreman's telephone would be activated and the process would be re-evaluated. A review of the relative documents showed that the last documented incidence of the action level of more than three out of ten carcasses with visible fecal contamination had been October 13, 1999, thirty months prior to this audit. The Auditor observed three out of ten quarters ready for shipping that had visible fecal contamination. These quarters had passed not only inspection on the slaughter line, but also pre-shipping inspection. Furthermore, visible fecal contamination and/or pieces of hide were observed on approximately 30% of beef halves on the first rail examined in the coolers, and also on two tails that were ready for packing. The DVFA officials ordered re-inspection of all the carcasses and the tails.

- Beef tails in Est. 34 routinely contacted equipment at the bung-dropping station. No corrective actions were taken.

Basic Facilities

- Neither of the two leggers on the slaughter line in Est. 34 had a hand soap dispenser. The DVFA officials ordered prompt correction.

- Lighting was found to be inadequate at all inspection stations in Est. 34. The European Commission regulations require 540 Lux, or 49 foot-candles (fc) of light. The Auditor measured 35 fc at the head lymph nodes, 30 fc on beef necks, 20 fc on the viscera tray, and only 10 fc in abdominal cavities. The DVFA officials ordered prompt correction.

Product Handling and Storage

- In Est. 34, a large stainless steel combo bin of edible product (trimmed fat) had been left uncovered and had been temporarily placed outside the establishment. The Veterinarian-In-Charge condemned the product.

Product-Contact Equipment

- Inadequately cleaned product-contact equipment had passed establishment pre-operational sanitation inspection and was ready for use in Ests. 34, 71, and 190. DVFA inspection personnel ordered re-cleaning of the equipment; the re-cleaning was again inadequate in Est. 190.

- Large plastic containers for edible product were routinely placed directly on the floor in Ests. 34 and 205, and a number of these containers, that had not been adequately cleaned, were stacked and ready for use. The DVFA officials ordered corrective actions and agreed to ensure continued resolution of the problem.

- Some stainless steel combo bins in Ests. 34 and 205 had cracks and torn corners. The Veterinarians-In-Charge ordered repair or replacement.

Equipment Sanitizing

- In Est. 34, several butchers on the slaughter line were observed to fail to sterilize their knives after making opening skin cuts before continuing their skinning operations. The DVFA officials ordered corrective actions, but they were not effective immediately.

Over-Product Equipment

- Maintenance and cleaning of some over-product equipment had been neglected in several areas in Ests. 71, 190, 205, and 469. This was a partial repeat finding in Est. 71; similar deficiencies had been observed in other areas during the March-April FSIS audit, but those areas had received the appropriate attention. The management representatives gave assurances they would extend the improved maintenance procedures to the newly-identified problem areas.

Personal Hygiene

- The establishment worker examining beef quarters for visible contamination prior to shipping in Est. 34 did not wash his hands after handling contaminated trimmings, thus further contaminating product. Corrective actions were attempted twice by the establishment management, and were ineffective both times. Also, the establishment worker responsible for trimming visible contamination on the slaughter line (in the same establishment) did not wash his hands after handling contaminated trimmings, thus further contaminating product. The DVFA officials ordered immediate corrective action.

Non-Food Storage Areas

- Grossly excessive, falling snow was present in one of the two freezers entered during the audit. Many cartons of product were thickly covered with snow. No corrective actions were taken.

- There were obvious holes in roughly a quarter of the ceiling tiles in the dry storage room in Est. 190. The management official expressed willingness to program repairs.

- Cleaning compounds in Est. 190 were stored under insanitary conditions. No corrective actions were taken.

Other Sanitation Deficiencies in Individual Establishments

- In April 2001, a high total plate count (TPC) was reported in a routine water sample (440 reported; 200 acceptable) in Est. 172, a cold store. The establishment was not informed immediately by telephone or fax, but rather by normal mail; system inspection and re-sampling were recommended. The water reticulation system was inspected and several valves replaced. The new sample was taken 22 days after the report was received. The TPC was now 150 (within tolerance). The results were reported within 48

hours. Inspection officials proposed contacting the laboratory to ensure more prompt reporting of potential problems.

- One coliform colony grew in a routine water sample taken in Est. 311 on Dec. 3, 2001; the results were not reported immediately by telephone or fax, but rather by normal mail. The results were not received by the establishment until Dec. 18. An immediate resampling was done; the system was chlorinated and flushed; the results were also reported through the mail. (This was not seen as a sanitation deficiency, but the results should have been reported by the laboratory much more promptly. The DVFA officials stated that they would ensure more prompt reporting of potentially problematical results.)

In addition, audits of documents from the 19 establishments not visited on-site revealed the following SSOP deficiencies:

- The Veterinarian-In-Charge of Est. 62 reported that the establishment did not adequately document findings and corrective actions regarding (frequent) condensation problems, but that improvement was underway.

- In Est. 192, a cold store, pre-operational sanitation was not specifically addressed in the written plan, nor had a form to document this activity been developed. The Regional Director gave assurances that he would communicate this requirement to the Veterinarian-In-Charge of this establishment for immediate implementation.

- In Ests. 192 and 865, the individuals responsible for the sanitation in the various areas had not been adequately specified in the written SSOP plan. The DVFA officials gave assurances that this would be corrected immediately.

ANIMAL DISEASE CONTROLS

Denmark's inspection system had controls in place to ensure adequate animal identification, ante-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned product. One deficiency was noted:

- The head inspector in Est. 34 was routinely making only one rapid incision into some beef head lymph nodes and was not adequately observing the cut surfaces. The DVFA officials corrected this immediately.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

RESIDUE CONTROLS

Denmark's National Residue Testing Plan for 2002 was being followed, and was on schedule. The Danish inspection system had adequate controls in place to ensure compliance with residue sampling and reporting procedures and use of chemicals.

- Cleaning compounds in Est. 190 were stored on a very rusty metal shelf in a storage room that opened directly into the main boning room. No corrective actions were taken.

SLAUGHTER/PROCESSING CONTROLS

The Danish inspection system had controls in place to ensure adequate humane handling and slaughter; ingredients identification; formulations; packaging materials; laboratory confirmation; label approvals; inspector monitoring; processing schedules, equipment and records; post-processing handling; processing defect actions by establishment personnel; and processing control by inspection personnel.

HACCP Implementation

All slaughter and processing establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspec-tion program. The data collection instrument used accompanies this report (Attachment B).

The DVFA veterinary authorities, in a communication of the discussions held during the exit meeting from the March-April 2001 FSIS audit, reinforced, in the regional offices, the need for Pre-Shipment Document Reviews (PSDRs) on April 19, 2001, and a letter went to the regional offices from the central authority in October 2001, urging the field inspection personnel to ensure that they were implemented in all establishments certified as eligible to export to the USA. Their use was implemented in Establishment 30 in July 2001. No product was exported to the U.S. from this establishment prior to the implementation of PSDRs. PSDRs were first implemented on January 11, 2002 in Est. 205. No product was exported directly to the U.S. from this establishment, but products routinely were sent to a sister establishment for U.S.-eligible further production. PSDRs were first implemented on January 8, 2002 in Est. 211. Product had been manufactured for and exported to the United States prior to that time. Note: in all three of these establishments, prior to the implementation of PSDRs, monitoring of critical limits had been reliably performed and documented.

The HACCP programs were found to meet the basic FSIS regulatory requirements, with the following exceptions in the establishments audited on-site:

- In Est. 34, the written HACCP plan called for the designated carcass trimmer, whose position on the slaughter line was immediately after the carcass inspector, to document the incidence of fecal contamination. This was not being done. The establishment was relying on the final carcass inspector to document electronically the fecal contamination

he observed, and when the more than four out of ten consecutive carcasses were noted with fecal contamination, an alarm on the foreman's telephone would be activated. The Auditor observed three out of ten quarters ready for shipping that had visible fecal contamination. These quarters had passed not only inspection on the slaughter line, but also pre-shipping inspection. Furthermore, visible fecal contamination and/or pieces of hide were observed on approximately 30% of beef halves on the first rail observed in the coolers. The DVFA officials ordered re-inspection of all the carcasses. Note: the last documented incidence of the action level of more than 4 out of 10 carcasses with visible fecal contamination was October 13, 1999.

- The establishment management in Est. 190 was not documenting the monitoring of the CCP for absence of visible contamination of product at receiving. (Obvious contamination with ingesta was observed on a beef quarter in the cooler, that had, according to the documentation, been inspected by the responsible establishment official and passed.) DVFA ordered immediate implementation of the required documentation.

- In Est. 190, documentation of corrective actions was frequently inadequate. Also, preventive measures were not included in the corrective action documentation. Documentation of the Critical Limits for temperatures in the coolers and freezers had improved since the previous FSIS audit, but documentation of corrective actions when critical limits were exceeded was still in need of further improvement; DVFA ordered prompt compliance.

- The management officials of Est. 190 had not developed verification procedures to ensure that the HACCP plan was working as intended to prevent product contamination. This was a repeat finding. The FSIS auditor discussed the requirement both in the establishment and during the exit meeting in Copenhagen, and the DVFA officials gave assurances the requirement would be promptly met.

- Only one HACCP plan had been developed in Est. 311 that covered all products, some of which had different critical limits for temperature (for different customers) at shipping. Other HACCP plans with multiple critical limits were observed in Est. 205. DVFA Officials agreed to ensure that separate HACCP plans would be developed for each product.

- In Est. 71, documentation of the Critical Limits for temperatures in the coolers and freezers had improved, but documentation of corrective actions when critical limits were exceeded was still in need of further improvement.

- The establishment official performing the pre-shipment document review in Ests. 190 (with 18 employees) and 865 (30 employees) was the same person who monitored the critical limits. DVFA officials stated that they would try to ensure that this is corrected.

In addition, audits of documents from the 19 establishments not visited on-site revealed the following HACCP deficiencies:

- Preventive measures were not included in the corrective action documentation in Est. 170. DVFA ordered correction.

- Corrective actions were not described in the HACCP plan for Est. 281. DVFA ordered correction.

- The management officials of Est. 281 had not developed verification procedures to ensure that the HACCP plan was working as intended to prevent product contamination. The FSIS auditor discussed the requirement both in the establishment and during the exit meeting in Copenhagen, and the DVFA officials gave assurances the requirement would be promptly met.

- In Est. 260, multiple processes (including heat-treated-ready-to-eat products and lard for use in other products) were incorporated into one HACCP plan with different CLs for temperature in the coolers. Also, in Est. 170, One HACCP plan covered all products, some of which had different critical limits for temperature at shipping. DVFA Officials agreed to ensure that separate HACCP plans would be developed for each product.

- The management of Est. 211 had "identified" 17 "CCPs," a number of which did not meet the definition of CCPs, e.g., temperature of product and starter cultures at reception, analysis of the starter cultures, etc. A new professional had been hired to re-evaluate the entire HACCP program in the immediate future. The management of Est. 205 had also designated several "CCPs" that did not meet the definition. The DVFA officials assigned to the establishments indicated that they understood the requirements and would ensure that revised program would meet them.

Testing for Generic *E. coli*

Three of the establishments audited on-site and five of those selected for document review were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

Denmark had adopted the FSIS regulatory requirements for generic *E. coli* testing with the exception of the following different equivalent requirements:

1. SAMPLING TOOLS

- Denmark was using a gauze swab sampling tool. The gauze swab is a generally/ internationally recognized sample collection tool for *E. coli* on meat or poultry product surfaces.

- The sampling tool is sensitive enough to gather *E. coli* that are present at the sample sites.

- The sampling tool does not contaminate the surfaces of the carcass.

2. ANALYTICAL METHODS: different methods.

- Denmark was using an NMKL method to analyze for generic *E. coli*. This method is a quantitative method of analysis.

- The method is approved by the AOAC International or an internationally recognized scientific organization.

Additionally, establishments had adequate controls in place to prevent meat products intended for Danish domestic consumption from being commingled with products eligible for export to the United States.

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements, with the following exception:

♦ In Est. 34, the establishment management had not developed a statistical process control procedure for the evaluation of the results for *E. coli* testing; they were mistakenly using the method reserved for excision sampling. This was discussed in detail both during the establishment audit and at the country exit meeting. The DVFA officials notified the inspection personnel in all establishments certified as eligible for export to the U.S. within 48 hours of this finding in Est. 34.

ENFORCEMENT CONTROLS

Inspection System Controls

The DVFA inspection system controls were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. These controls included animal identification, ante-and post-mortem inspection dispositions, control of restricted product and inspection samples, condemned and restricted product control, control of restricted product and inspection samples, boneless meat reinspection, control and disposition of dead, dying, diseased or disabled animals, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans—see the exception noted above for Est. 71), and inspection supervision and documentation. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

No meat imported from other countries, or meat from live animals imported from other countries, was used in any product eligible for export to the United States.

The Auditor conducted discussions in the field with central and regional DVFA officials regarding the re-packaging of damaged cartons at cold-storage facilities when the inner liners were intact so that the meat was not exposed. Some of these facilities had been allowed to re-package the contents of these damaged cartons into new cartons supplied to the cold-storage facilities by the establishment(s) of origin, removing the original label and affixing it to the new carton. DVFA officials in the region of Nordjylland had developed a new label that bore the statement: "Opened and re-sealed by the Veterinary Control Officials," with space for an original signature of the Veterinarian-In-Charge of the cold-storage facility and for an official seal, bearing the establishment number of the cold-storage facility. There was a proposal to extend the use of this new re-packaging system to the rest of the Danish regions. (All damaged cartons whose contents were exposed were returned to the establishment(s) of origin for reinspection and eventual repacking.)

In general, field DVFA officials were documenting their monitoring of the establishments' fulfilling of their responsibilities, but this documentation was in need of some improvement, especially in smaller establishments and cold-storage facilities.

Furthermore the Auditor determined that, in general, the DVFA officials in positions of authority, both in the central offices in Copenhagen and in the various regional offices had a good understanding of the requirements of HACCP systems in the establishments. The field officials, whose assignments involved direct daily oversight of establishment operations, also demonstrated an adequate understanding of the requirements; however, more evaluation of some of the establishments' HACCP plans—especially those of smaller, private companies—was indicated to help to eliminate unnecessary and/or excessive content.

- The Veterinarian-In-Charge in Est. 34 demonstrated a plan for his staff to conduct weekly verification of ten establishment activities. For all but one of the categories, verifications had not been performed during the majority of the eight weeks that had elapsed since the beginning of the year. During three of the eight weeks, none of these activities, including verification of controls for fecal contamination and operational sanitation, had been performed. Note: visible fecal contamination was one of the major concerns during the audit of this establishment.

The following enforcement concerns were identified:

- A letter was sent to all the heads of the regional offices in April 2001, shortly after the previous FSIS audit, informing them of concerns that had arisen as a result of the audit, including the need for pre-shipment document reviews (PSDRs). The field officials were informed through meetings held by the regional officials approximately in May 2001. There were varying degrees of confusion regarding the nature of the requirement, with the result that, especially in smaller, private establishments, the requirement was not fulfilled until late summer or autumn. As an example of extreme delays in implementation, the PSDR requirement was not met in Est. 236 until December 2001, and in Est. 211 until January 8, 2002, but product had been manufactured for and exported to the United States prior to that time. The central and regional DVFA officials present at the audit of the documents for these establishments readily agreed that they had not adequately

followed up on the establishments' fulfilling of this requirement, but stated that they were confident that all establishments certified as eligible for U.S. export had, as of the time of this audit, developed and implemented PSDRs.

♦ A document review of Est. 62 showed that the Veterinarian-In-Charge, who had been assigned to the plant for only some three months, was not adequately documenting establishment noncompliance regarding (frequent) condensation problems, corrective actions, and preventive measures. There was some documentation, but it had not been effective in ensuring that the establishment must get the problems under control.

Testing for *Salmonella* Species

Four of the establishments audited on-site and seven of those selected for document review were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Denmark had adopted the FSIS regulatory requirements for *Salmonella* testing with the exception of the following equivalent measures:

1. SAMPLE COLLECTOR: establishments take samples.

- The government of Denmark provides a clearly written sampling plan with instructions for sample collection and processing that is followed by all applicable export establishments.
- All applicable veterinarians are properly and uniformly trained; they train the establishment employees. The trained veterinarian observes the collection/storage/ transport procedures on a periodic, unannounced basis to ensure that FSIS requirements are met. The government ensures that establishment sample collection activities are appropriate. Sample verification is performed upon request by the DVFA where the official veterinarian collects samples and DVFA analyzes the sample.

- The government of Denmark uses the test results to monitor establishment performance over time.

- The government of Denmark takes immediate action any time an establishment fails to meet *Salmonella* performance standards.

2. LABORATORIES: private laboratories analyze samples.

- The laboratories are independent non-government or establishment laboratories that are accredited by the government of Denmark. The laboratories are required to participate in performance testing to ensure laboratory analyses are properly performed. Establishment labs are under the direct supervision of the on-site veterinarian.

- All accredited laboratories have a formal program to ensure that lab personnel are properly trained, there are suitable facilities and equipment, there is a written quality assurance program, and there are adequate reporting and record keeping facilities.

- Test results are provided directly to the government veterinarian.

3. SALMONELLA TESTING STRATEGY.

- Denmark uses a continuous, ongoing sampling program to determine when to initiate additional *Salmonella* testing. The sampling methodology is based on a uniform system approach in all applicable export establishments. All U.S. export establishments are included in the sample pool. Denmark collects one sample per production day, grouped in sample sets of 55 samples (swine) and uses FSIS Performance Standards and enforcement procedures.

- Denmark uses a continuous, on-going sampling program to determine when to initiate additional *Salmonella* testing. All products for which there is a U.S. performance standard are included in the sample pool.

- Denmark's testing program has statistical criteria for evaluating test results.

- The percentage of *Salmonella* positives over time meets the FSIS percentage of positives in the FSIS standard.

4. SAMPLING TOOLS.

- The gauze pad sampling tool is used. This sampling tool is internationally recognized for sampling *Salmonella* on meat or poultry product surfaces.

- The sampling tool is sensitive enough to gather *Salmonella* that are present at the sample sites.

- The sampling tool does not contaminate the surfaces of the carcass.

Furthermore, the official veterinarian in each slaughter establishment was taking an independent sample once weekly for *Salmonella* analysis. These official samples served as verification of those taken by the establishments, and were analyzed at an official laboratory.

Species Verification Testing

At the time of this audit, Denmark was not exempt from the species verification requirement. The auditor verified that species verification was being conducted in accordance with FSIS requirements, with one exception:

- No species verification was performed on product from Est. 205, although both pork and beef were processed.

Monthly Reviews

FSIS requires documented supervisory visits by a representative of the foreign inspection system to each establishment certified as eligible to export to the United States, not less frequently than one such visit per month, during any period when the establishment is engaged in producing products that could be used for exportation to the United States.

The systems in place for the completion of, and the responsibility for, the monthly reviews was found to vary considerably between the meat inspection regions:

In the region of ***Ringsted***, which had six establishments (25, 26, 30, 41, 183, 195) listed for U.S.-export, the monthly internal reviews were being conducted by the Veterinarians-In-Charge at other U.S.-listed establishments in the region. The Head of the regional office of the Food Inspection Service in Ringsted designated which veterinarians were to have this responsibility. These internal auditors submitted copies of their reports to the regional offices for review.

In the region of ***Fyn***, there were three designated individuals who performed the monthly reviews of the five establishments certified for U.S. export (29, 45, 175, 187, and 198). In the region of ***Sønderjylland,*** a regional veterinarian had the responsibility to conduct the monthly reviews of the 13 establishments in the region certified for U.S. export (14, 101, 171, 177, 178, 179, 186, 190, 305, 311, 318, 319, and 879), and was assigned this duty by the head of the regional office of DVFA.

In the region of ***Esbjerg,*** the Veterinarians-In-Charge at Ests. 53 and 340 were conducting the monthly internal reviews of each other's assigned establishments. Two officials from the regional office share the duty of conducting the monthly internal reviews of the other four plants certified for US-export.

In the region of ***Herning,*** the internal reviews of the six establishments (15, 31, 38, 60, 188, and 281) certified for U.S. export were conducted by three officials from the regional office. The reviewers' reports were submitted to a supervisor, who was based in the regional office in Herning. She reviewed the contents of the reports and discussed the findings with the reviewing officers.

In the region of ***Viborg,*** the monthly internal reviews of the eleven establishments certified for U.S. export (47, 78, 79, 85, 126, 172, 180, 215, 300, 338, and 339) were conducted by three Veterinarians-In-Charge (VIC) and one Deputy Veterinarian-In-Charge of three of these establishments. An internal review of an establishment was never conducted by the VIC in that establishment. The reviewers' reports were submitted to a supervisor, who was based in the regional office in Viborg. She reviewed the contents of the reports and discussed the findings with the reviewing officers, at least

once per month. A vacancy announcement had been advertised for a regional official responsible for the internal reviews, there had been applications, and a selection had been made, but a temporary hiring freeze had delayed the final filling of the position.

In the region of ***Nordjylland,*** under the system in place at the time of the audit, the monthly internal reviews of the four slaughter establishments certified for U.S. export (Ests. 13, 28, 62, and 71) were being conducted by the Veterinarians-In-Charge of these establishments. An internal review of an establishment was never conducted by the VIC in that establishment. The internal reviews of the other eleven (non-slaughter) establishments certified for U.S. export (72, 165, 191, 196, 211, 236, 262, 286, 337, 377, and 469) were conducted by the same four VICs of the slaughter establishments, two other veterinarians in charge of poultry slaughter establishments, and one regional veterinarian. The VIC in each of the four slaughter establishments had the responsibility for supervision of the activities in several of the eleven smaller plants; however, the internal reviews of each of these smaller plants was to be conducted by a different veterinarian.

In the region of ***Aarhus,*** as of January 1, 2001, one veterinarian from the regional office had had the assignment of performing the internal reviews of the establishment certified to export to the U.S. He had been assisted in some of these internal reviews by the Veterinarian-In-Charge of Establishment 220 in Brabrand and also by two other veterinarians from the regional office.

In the region of ***Vejle,*** there were 12 establishments listed for U.S. export (Ests. 32, 58 , 65, 161, 189, 192, 260, 315, 456, 272, 865, and 4485. The monthly internal reviews in this region were performed by two regional officials, three Veterinarians-In-Charge in slaughter establishments, and one veterinarian who was an assistant to one of these Veterinarians-In-Charge. The veterinarians other than the regional officials never conducted the reviews of establishments in which they were stationed, and the reviews of any given establishment were performed, in different months, by different reviewers. The reviewers' reports were submitted to a supervisor, who was based in the regional office in Vejle. He evaluated the contents of the reports and discussed the findings with the reviewing officers. In this region, the monthly review reports were sent only to the Veterinarian-In-Charge of the establishment reviewed, not to the plant management, and these reports contained summaries of the reviews of the supervisional activities of the in-plant inspection personnel.

Monthly internal review documents examined during this audit were complete and thorough in the regions of Ringsted, Herning, Viborg, and Vejle. In Fyn, none had been performed at Est. 175 in March 2001; this was a cold store facility, and the veterinarian assigned to perform the monthly review was accompanying the U.S. auditor during that month. In Sønderjylland, there were no internal reviews in Est. 190 during the months of June, July, or October 2001, and none in Ests. 177 and 179 (a cold store) during April, June, or July. In Esbjerg, there was no internal review in Est. 170 in May 2001, due to a misunderstanding between the two regional reviewers. In Nordjylland, there were no internal reviews in Est. 71 in November 2001, due to illness; in May 2001 in Est. 191 (a cold store) due to a

misunderstanding involving a change in Veterinarians-In-Charge, and for Est. 469 for the months of July, August, or September 2001, although there was supporting documentation that the supervisory reviewer had paid several visits to the establishment during each of those months. In the Århus region, there were no monthly supervisory reports for Est. 194 (a cold-storage facility) for the months of March, May, June, August, November.

The current system for distribution of the monthly reports in most of the areas of the country was that the findings were sent directly to the establishment management by the internal reviewer, and any comments regarding the findings of the supervision of the in-plant inspection service personnel were attached and this extended report was sent to the Veterinarian-In-Charge of the establishment. A new system was being implemented, under which only one copy of the report would be provided directly to the Veterinarian-In-Charge, and it would then be his/her responsibility to report the contents of the findings relative to the establishment to the management and discuss the issues.

The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the offices of the Regional Authorities.

In the region of Viborg, there had been no documentation of the supervision of the routine activities of DVFA staff in the field. Their performance, as well as establishment compliance, had been routinely evaluated during the monthly visits, however. With the expected hiring of a dedicated internal reviewer, this was expected to improve in the near future. In the region of Nordjylland, supervision of the performance of the inspection staff in this region was documented only if concerns were identified.

The Auditor examined the internal review reports generated during the previous year for both the establishments selected both for on-site audits and for those selected for document audits. These internal reviews were conducted each month when U.S.-eligible production was conducted or, in cold-storage facilities, when U.S.-eligible product was stored, at 22 of these 30 establishments, and determined that the supervisory visits had been missed for one month in four establishments, for three months in three establishments, and for five months in one establishment. The requirement that the internal reviews are to be performed each month when U.S.-eligible production is conducted or, in cold-storage facilities, when U.S.-eligible product was stored, was emphasized during the meetings with inspection personnel both in the field and in the exit meeting in Copenhagen. The DVFA officials gave assurances that they were aware of the requirement and would ensure that they would be conducted on a monthly basis, at a minimum.

Enforcement Activities

The Danish Veterinary and Food Administration publishes an extensive summary of the Agency's enforcement activities in the form of a compliance report on their Website. This report is very similar in scope and content to the Quarterly Enforcement Report published on FSIS's Website.

Exit Meeting

An exit meeting was conducted in Copenhagen on February 28, 2002. The Danish participants were Dr. Birgitte Povlsen, Senior Veterinary Officer and Head of the Division for Import/Export; Dr. Jens Munk Ebbesen, Deputy Head of the Division for Import/Export; Dr. Mette Nyborg, Veterinary Officer and Deputy Head of the Division for Food Safety; Dr. Henning Pedersen, Veterinary Officer, Division for Import/Export; Ms. Susanne J Jensen, Food Scientist, Division for Food Safety. FSIS was represented by Dr. Gary D. Bolstad, International Audit Staff Officer. The findings encountered in the course of the audits were discussed and the DVFA officials gave assurances that, in addition to reinforcing the corrective actions taken in response to the various deficiencies found during the audits:

1. Considerably more effort would be devoted to "over-the-shoulder" supervision of the activities of field inspection personnel to help to detect problems such as those encountered in the two unacceptable establishments in earlier stages of development.

2. Adequate light would be ensured at all inspection stations.

3. Increased attention would be paid to the maintenance and cleaning of over-product equipment.

4. Improvements would be implemented promptly in those establishments in which the documentation SSOP activities had been found deficient.

5. Documented internal reviews of all establishments would be conducted during all months in which production of U.S.–eligible product takes place.

CONCLUSION

The inspection system of Denmark was found to have effective controls in place, or adequate corrective actions were taken, to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Eleven establishments were audited on-site: nine were acceptable and two were evaluated by the Danish meat inspection officials as unacceptable and were removed by them from the list of establishments certified as eligible to export to the U.S.; neither of the latter was producing any product that was exported to the United States. All deficiencies encountered during the on-site audits of the acceptable establishments were adequately addressed to the Auditor's satisfaction.

Dr. Gary D. Bolstad
International Audit Staff Officer

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing
D. Data collection instrument for *Salmonella* testing
E. Laboratory Audit Forms
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report (when it becomes available)

Attachment A-1

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
34	√	√	√	√*	√	√	√	√
71	√	√	√	√*	√	√	√	√
165	√	√	√	N/A	√	√	√	√
172	√	√	√	N/A	√	√	√	√
179	√	√	√	N/A	√	√	√	√
190	√	√	√	√*	√	√	√*	√
191	√	√	√	N/A	√	√	√	√
205	√	√	√	√	√	√	√	√
286	√	√	√	√	√	√	√	√
311	√	√	√	√	√	√	√	√
469	√	√	√	√	√	√	√	√

34, 71, 190: Contact surfaces were addressed in the written SSOPs, but inadequately-cleaned contact surfaces were observed during the audits.

190: Documentation of corrective actions was, at times, inadequate; preventive measures were not included in the corrective action documentation. Documentation by the Veterinarian-In-Charge indicated that the establishment's pre-operational sanitation inspections were inadequate approximately every second time he conducted his (bi-weekly) independent pre-operational sanitation checks.

Documentation was also audited from the following establishments that were not visited on-site:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
30	√	√	√	√	√	√	√	√
31	√	√	√	√	√	√	√	√
32	√	√	√	√	√	√	√	√
45	√	√	√	√	√	√	√	√
53	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√*	√
170	√	√	√	√	√	√	√	√
175	√	√	√	N/A*	√	√	√	√
177	√	√	√	N/A*	√	√	√	√
187	√	√	√	N/A*	√	√	√	√
192	√	NO	√	N/A*	√	NO	Inad.*	√
194	√	√	√	N/A*	√	√	√	√
196	√	√	√	N/A*	√	√	√	√
211	√	√	√	√	√	√	√	√
215	√	√	√	√	√	√	√	√
236	√	√	√	√	√	√	√	√
260	√	√	√	√	√	√	√	√
281	√	√	√	√	√	√	√	√
865	√	√	√	√	√	NO	√	√

Column 7: The DVFA inspection officials provided examples of verification that the establishments' documentation was performed as required.

62 The Veterinarian-In-Charge reported that the establishment did not adequately document findings and corrective actions regarding (frequent) condensation problems, but that improvement was underway.

175, 177, 187, 192, 194, 196 These were strictly cold-store facilities. There were no product-contact surfaces.

192 A form to document pre-operational sanitation had not been developed.

Attachment B-1

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing and documenting pre-shipment document reviews as required.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

Est. #	1. Flow diagram	2. Haz. analysis –all ID'ed	3. Use & users includ-ed	4. Plan for each product	5. CCPs for all hazards	6. Mon-itoring is spec-ified	7. Corr. actions are des-cribed	8. Plan valida-ted	9. Ade-quate verific. proced-ures	10. Ad-equate docu-menta-tion	11. Dat-ed and signed	12. Pre-ship-ment doc. re-views
34	√	√	√	√	√	√	√	√	√	NO	√	√
71	√	√	√	√	√	√	√	√	√	√*	√	√
165	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
172	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
179	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
190	√	√	√	√	√	√	√	√	NO	NO	√	√
191	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
205	√	√	√	NO	√	√	√	√	√	√	√	√
286	√	√	√	√	√	√	√	√	√	√	√	√
311	√	√	√	NO	√	√	√	√	√	√	√	√
469	√	√	√	√	√	√	√	√	√	√	√	√

71—Documentation of the Critical Limits for temperatures in the coolers and freezers had improved, but documentation of corrective actions when critical limits were exceeded was still in need of further improvement.

205—HACCP plans had individual CCPs with multiple critical limits.

311— One HACCP plan covered all products, some of which had different critical limits for temperature at shipping. DVFA agreed to ensure that separate HACCP plans would be developed for each product.

Documentation was also audited from the following establishments that were not visited on-site:

Est. #	1. Flow diagram	2. Haz. analysis –all ID'ed	3. Use & users include-ed	4. Plan for each product	5. CCPs for all hazards	6. Mon-itoring is spec-ified	7. Corr. actions are des-cribed	8. Plan valida-ted	9. Ade-quate verific. Proced-ures	10. Ade-quate docu-menta-tion	11. Dat-ed and signed	12. Pre-ship-ment doc. re-views
30	√	√	√	√	√	√	√	√	√	√	√	√
31	√	√	√	√	√	√	√	√	√	√	√	√
32	√	√	√	√	√	√	√	√	√	√	√	√
45	√	√	√	√	√	√	√	√	√	√	√	√
53	√	√	√	√	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√	√	√	√	√	√
170	√	√	√	NO	√	√	√	√	√	√*	√	√
175	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
177	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
187	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
192	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
194	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
196	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
211	√	√	√	√	√*	√	√	√	√	√*	√	√*
215	√	√	√	√	√	√	√	√	√	√	√	√
236	√	√	√	√	√	√	√	√	√	√	√	√
260	√	√	√	NO	√	√	√	√	√	√	√	√
281	√	√	√	√	√	√	NO	√	NO	√	√	√
865	√	√	√	√	√	√	√	√	√	√	√	√

170—One HACCP plan covered all products, some of which had different critical limits for temperature at shipping. DVFA agreed to ensure that separate HACCP plans would be developed for each product. Also, in this establishment, the IIC stated that documentation was done daily, but that it did not routinely include description of preventive measures; he stated that he would ensure that these are included.

211— (5) The establishment had "identified" 17 "CCPs," a number of which did not meet the definition of CCPs, e.g., temperature of product and starter cultures at reception, analysis of the starter cultures, etc. A new professional had been hired to re-evaluate the entire HACCP program in the immediate future. The DVFA officials assigned to the establishment indicated that they understood the requirements and would ensure that the new program would meet them. (10) Documentation of corrective actions did not include preventive measures. (12) The Pre-Shipment Document Review requirement was not met until January 8, 2002, but product had been manufactured for and exported to the United States prior to that time.

260—Multiple processes (including heat-treated-ready-to-eat products and lard for use in other products) were incorporated into one HACCP plan with different CLs for temperature in the coolers

Attachment C-1

Data Collection Instrument for Generic *E. coli* Testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is/are being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
34	√	√	√	√	√	√	√	√	√*	√
71	√	√	√	√	√	√	√	√	√	√
165	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
172	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
179	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
190	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
191	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
205	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
286	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
311	√	√	√	√	√	√	√	√	√	√
469	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

34 The establishment management had not developed a statistical process control procedure for the evaluation of the results; they were mistakenly using the method developed for excision sampling.

Documentation was also audited from the following establishments that were not visited on-site:

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
31	√	√	√	√	√	√	√	√	√	√
32	√	√	√	√	√	√	√	√	√	√
45	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
53	√	√	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√	√	√	√
170	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
175	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
177	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
187	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
192	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
194	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
196	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
211	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
215	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
236	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
260	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
281	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
865	√	√	√	√	√	√	√	√	√	√

Attachment D-1

Data Collection Instrument for *Salmonella* testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
34	√	√	N/A	√	√	N/A
71	√	√	N/A	√	√	N/A
165	N/A	N/A	N/A	N/A	N/A	N/A
172	N/A	N/A	N/A	N/A	N/A	N/A
179	N/A	N/A	N/A	N/A	N/A	N/A
190	N/A	N/A	N/A	N/A	N/A	N/A
191	N/A	N/A	N/A	N/A	N/A	N/A
205	√	N/A	√	√	√	N/A
286	N/A	N/A	N/A	N/A	N/A	N/A
311	√	√	N/A	√	√	N/A
469	N/A	N/A	N/A	N/A	N/A	N/A

Documentation was also audited from the following establishments that were not visited on-site.

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
30	√	N/A	√	√	√	N/A
31	√	√	N/A	√	√	N/A
32	√	√	N/A	√	√	N/A
45	N/A	N/A	N/A	N/A	N/A	N/A
53	√	√	N/A	√	√	N/A
62	√	√	N/A	√	√	N/A
170	N/A	N/A	N/A	N/A	N/A	N/A
175	N/A	N/A	N/A	N/A	N/A	N/A
177	N/A	N/A	N/A	N/A	N/A	N/A
187	N/A	N/A	N/A	N/A	N/A	N/A
192	N/A	N/A	N/A	N/A	N/A	N/A
194	N/A	N/A	N/A	N/A	N/A	N/A
196	N/A	N/A	N/A	N/A	N/A	N/A
211	N/A	N/A	N/A	N/A	N/A	N/A
215	N/A	N/A	N/A	N/A	N/A	N/A
236	N/A	N/A	N/A	N/A	N/A	N/A
260	√	N/A	√	√	√	N/A
281	N/A	N/A	N/A	N/A	N/A	N/A
865	√	√	√	√	√	N/A